

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Norfolk Division**

**ELI LILLY AND COMPANY,**

**Plaintiff,**

**v.**

**Civil No. 2:07cv450**

**SYNTHON LABORATORIES, INC.,**

**Defendants.**

**ORDER AND OPINION**

This matter is before the Court on the Stipulation of Dismissal filed by plaintiff Eli Lilly and Co. (“Eli Lilly”) and defendant Synthon Laboratories, Inc. (“Synthon”). Doc. 57. Movant Mylan Pharmaceuticals, Inc. (“Mylan”) objects to this Stipulation, arguing that its pending Motion to Intervene should be decided before the Court allows dismissal of the case. Doc. 55.

For the reasons stated herein, the Court **FINDS** that the case should be dismissed.

**I. PROCEDURAL HISTORY**

Eli Lilly brought this case against Synthon alleging patent infringement after Synthon filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA) seeking to market a generic version of a drug produced by Eli Lilly.<sup>1</sup> Doc. 1. Eli Lilly then sought to stay the action, as it had filed an earlier action in the District of New Jersey against Synthon and nine (9) other defendants who also allegedly filed ANDAs. Doc. 11. Eli Lilly filed

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<sup>1</sup> This process is governed by the Drug Price Competition and Patent Restoration Act, commonly known as the Hatch-Waxman Act, and is set out at 21 U.S.C. § 355(j).

this action anticipating that Synthon would object to personal jurisdiction in New Jersey. Id. Synthon strenuously objected to Eli Lilly's Motion to Stay, claiming that delaying resolution would cause it substantial prejudice. See Doc. 24. Further factual and procedural background of this action are reviewed in detail in this Court's Order denying Eli Lilly's Motion to Stay issued January 29, 2008. Doc. 39.

On February 8, 2008 Mylan filed its Motion to Intervene as a Defendant. Docs. 40 (Motion) and 41 (Mem. in Support). Like Synthon, Mylan is a defendant in the parallel proceeding pending in the District of New Jersey. As noted in this Court's earlier order, trial in this case is scheduled for June 2008, while trial in the New Jersey action is not projected to begin until mid 2010. Doc. 39 at 7. Mylan argued in its Motion that its rights are equal to those of Synthon, and that if Synthon were successful in invalidating Eli Lilly's patent in this Court, Synthon would enjoy a one hundred eighty (180) day period of exclusivity to market its generic drug that Mylan is entitled to share, as both parties are first-filers of ANDAs. Doc. 41 at 2. This potential prejudice, argued Mylan, entitled it to intervene in this case either as of right or by permission. Doc. 41 at 12, 20. Eli Lilly filed an Opposition to this Motion on February 22, 2008 arguing that even though Mylan would suffer prejudice if Synthon is successful in this action, the Court should deny the Motion. Doc. 47. Eli Lilly also renewed its Motion to Stay. Id.; see also Docs. 11 and 12. Synthon filed an Opposition to the renewed Motion to Stay on February 28, 2008. Doc. 50. Synthon did not oppose Mylan's Motion to Intervene. Id. Mylan filed a reply to Eli Lilly's Opposition on February 26, 2008. Doc. 48.

A hearing on the Motion to Intervene was scheduled for March 5, 2008. On March 4, 2008, Eli Lilly and Synthon filed their Stipulation of Dismissal, stating that they had agreed to

dismiss the case without prejudice. Doc. 57. Mylan also filed its Notice of Intent to Object to the Stipulation of Dismissal on March 4, 2008. Doc. 56. The Court instructed the Clerk that the case should not be dismissed until Mylan's objection could be considered.

At the hearing on March 5, 2008 the Court heard argument on whether the pending Motion to Intervene prevented the dismissal without Mylan's consent. See Doc. 58. Mylan implied, both in its written objection and at the hearing, that Eli Lilly and Synthon had entered into a side agreement that resulted in the filing of the Stipulation of Dismissal. Mylan also argued that, prior to the attempted filing of the stipulation, Eli Lilly had offered to consent to its intervention and that Mylan had accepted this offer, creating a binding agreement between the parties as to intervention. Mylan additionally argued that it had acted as a de facto party to this action by participating in discovery and that Eli Lilly was forum shopping by trying to prevent the case from proceeding in this Court. Eli Lilly argued that the Stipulation of Dismissal was effective without the Court's approval or Mylan's consent under Fed. R. Civ. P. 41(a)(1). Eli Lilly stated that as the Court had not yet ruled on Mylan's Motion to Intervene, Mylan was not a party, and had no standing to object to the Stipulation of Dismissal. Eli Lilly further argued that Mylan's "acceptance" of Eli Lilly's offer to consent to the intervention added additional terms to the agreement, and was thus a counter-offer which did not create a binding agreement. Synthon agreed with Eli Lilly's statement of the law, and noted that circumstances had changed such that it was willing to consent to jurisdiction in New Jersey. Synthon also stated that it had informed Mylan a week and a half before the hearing that there was a possibility that a stipulation of dismissal would be filed.

The Court took the matter under advisement and requested that the parties and the movant

file additional briefing by Wednesday, March 12, 2008. Both of the parties and Mylan filed additional briefs. Docs. 60, 62, and 64. Synthon informed the Court that there was no side agreement with Eli Lilly, and that instead, it agreed to the dismissal for business reasons. Doc. 60 at 2. Eli Lilly argued that the Court lacked the authority to grant the Motion to Intervene, and that dismissal of the case would not prejudice Mylan, which would still be a defendant in New Jersey. Doc. 62 at 2. Eli Lilly also argued that Mylan engaged in fraud by concealing that it knew of Synthon's intention to stipulate to dismissal. Id. at 19. Mylan argued that the Court had the authority to grant Mylan's Motion to Intervene despite the filing of the Stipulation of Dismissal. Doc. 64. Mylan further stated that Eli Lilly and Synthon were engaging in forum shopping that undermined the purpose of the Hatch-Waxman Act. Id. at 17. Mylan also argued that its Motion to Intervene should be granted because Eli Lilly had consented to this Motion and further, Mylan would be prejudiced by delay if it were not permitted to intervene. Id. at 4-5.

## II. ANALYSIS

The timing of the filing of the Stipulation of Dismissal under Fed. R. Civ. P. 41(a), combined with the implication in Mylan's objection that a deal had been struck between Eli Lilly and Synthon raised serious questions for the Court. However, the implication that some unexplained consideration flowed from Eli Lilly to Synthon in return for the stipulation is not supported by the record before the Court. The difficult questions which the Court posed to Eli Lilly's counsel were satisfactorily answered by him at the March 5, 2008 hearing.

Mylan's allegations that Eli Lilly is guilty of forum shopping and its implications that Synthon received some consideration from Eli Lilly in exchange for its agreement to the Stipulation of Dismissal are simply not supported by the record. Similarly, Eli Lilly's allegation

of fraud against Mylan is not supported by the record. Eli Lilly has consistently sought to litigate this case in New Jersey, and only instituted suit in Virginia in anticipation of a potential jurisdictional issue being raised in New Jersey, which it later was. Eli Lilly's action in filing a separate suit in the Eastern District of Virginia and thereafter seeking a stay is simply an effort on its part to protect itself, not forum shopping or "gaming the system." For its part, Synthon changed its position one hundred and eighty degrees. After emphasizing the necessity of a prompt trial date and the importance of the public interest in same, Synthon now complains of having to proceed at "break-neck speed." At this stage of the proceeding, Synthon's position has no effect on the Court's ruling, and the question of whether its establishment of a presence in the Eastern District of Virginia should be a basis for venue in this district shall have to wait for another day. At this point, the Court will have to focus upon the positions advanced by Eli Lilly and Mylan.

The general rule is that parties have a right to dismiss a case of this nature on one occasion by agreement, without seeking prior approval of the Court. See Fed. R. Civ. P. 41(a)(1); see also In re Matthews, 395 F.3d 477 (4th Cir. 2005); Comacho v. Mancuso, 53 F.3d 48 (4th Cir. 1995). This is generally true even if a motion to intervene is pending and the potential intervenor objects. See GMAC Comm. Mortgage Corp. v. LaSalle Bank Nat'l Ass'n, 213 F.R.D. 150, 150-51 (S.D.N.Y. 2003); Mut. Produce, Inc. v. Penn. Central Trans. Co., 119 F.R.D. 619, 620-21 (D. Mass. 1988). However, the origin of this rule seems to be founded upon the views of a text writer and not upon binding or even persuasive precedent from an appellate court. See 8 James Wm. Moore et al., Moore's Federal Practice, § 41.34. There may indeed be circumstances where an intervenor could and should be treated as a de facto party and the Court

might invoke equitable principles to estop the stipulating parties from invoking a rule which would prejudice the rights of a party whose motion to intervene is pending. See Alternative Research and Dev. Found. v. Veneman, 262 F.3d 406, 411 (D.C. Cir. 2001); Fleet Capital Corp. v. Merco Joint Venture, LLC, No 02 CV 0279(ILG), 2002 WL 31528633, at \*4 (E.D.N.Y. Sept. 3, 2002).

This, however, is not a case where the Court finds it should invoke equitable principles. First of all, in its Motion to Intervene Mylan argued that it would be prejudiced if Synthon were successful in this action and achieved the rights of a first-filer. This concern no longer exists if Synthon is not litigating in this Court. Second, although Mylan has engaged in discovery in this case, such procedures were also applicable in the pending case in New Jersey, and thus Mylan cannot claim it was misled into devoting its resources to this proceeding. Third, Mylan will not be prejudiced by the dismissal of this action, except to the extent that the determination of its rights may be delayed. While delay is a matter of importance under the Hatch-Waxman Act, and should be a matter of importance in all civil litigation as delay is an important factor in the escalating costs of resolving civil disputes in federal courts, Mylan's rights are pending alongside those of all other ANDA filers in New Jersey. Finally, although counsel for Eli Lilly candidly concedes making an offer to withdraw its opposition to the intervention of Mylan, and there is substantial evidence that Mylan accepted this offer, the Court does not believe this is a proper case in which to invoke equitable principles to impose an estoppel upon Eli Lilly. Whether counsel reached a binding agreement is a fact intensive inquiry which the Court is not prepared to resolve on the basis of this record. If such an agreement were binding, its application would require the Court to invoke an equitable estoppel, which is not appropriate where there is

unchallenged evidence that a stipulated dismissal was under consideration prior to the alleged agreement. For these reasons, the Court **FINDS** that the filing of the Stipulation of Dismissal has the effect of dismissing this case.

### III. CONCLUSION

For the foregoing reasons, the Court **ORDERS** the Clerk to file the Stipulation of Dismissal (Doc. 57) which will operate as a dismissal under Fed. R. Civ. P. 41(a)(1)(A)(ii). As a result of this dismissal, the Motion to Intervene filed by Mylan (Doc. 40) and the Motion for Leave to File to Add Parties to the Complaint filed by Eli Lilly (Doc. 45) are **MOOT**.

The Clerk is **REQUESTED** to mail a copy of this Order to all counsel of record.

It is so **ORDERED**.

/s/

Henry Coke Morgan, Jr.  
Senior United States District Judge

 HENRY COKE MORGAN, JR.  
SENIOR UNITED STATES DISTRICT JUDGE

Norfolk, Virginia  
March 17, 2008